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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/671,697

09/29/2003

Jean-Yves Bonnefoy

1430-287

7814

23117

7590

12/20/2006

NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER

BASI, NIRMAL SINGH

ART UNIT

PAPER NUMBER

1646

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

12/20/2006

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/671,697

Applicant(s)

BONNEFOY ET AL.

Examiner

Nirmal S. Basi

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/29/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/29/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Amendment filed 8/14/06 has been entered. Preliminary Amendment filed 9/29/03 has been entered.

Election/Restrictions

2. Applicant's election with traverse of Group XVII (claims 21-22) in the reply filed on 8/14/06 is acknowledged. The traversal is on the ground(s) that it would not impose a serious burden to examine closely related inventions of Groups V to VIII and XVII. This is not found persuasive because the methods of Groups V to VIII and XVII are distinct for reasons given in the previous Office action. Therefore, there exists a serious search burden to examine the extra groups, V to VIII and XVII, as one invention. Accordingly, claims 1-20 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP 821.03.

The requirement is still deemed proper and is therefore made FINAL.

3. IDS filed 9/2/906 has been considered.
4. The drawings filed 9/2/903 have been approved by the examiner.
5. The Declaration/oath is objected to because it does not claim priority to U.S. Application number 08/969,125, 09/545,002 or foreign priority based on United Kingdom application 9625899.1 filed 12/13/06. The wording of an oath or declaration cannot be amended. If the wording is not correct or if all of the required affirmations have not been made or if it has not been properly subscribed to, a new oath or declaration is required. The new oath or declaration must properly identify the application of which it is to form a part, preferably by

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application number and filing date in the body of the oath or declaration. See MPEP 602.01 and 602.02. Appropriate correction is required.

6. The Brief Description of the Drawings is objected to because each Figure must be described separately. Figure 1A and 1B, must be described separately in the Brief Description of the Drawings, or the equivalent, as required by 37 C.F.R. 1.84 (u)(1).

Appropriate correction is required.

Claim Rejection, 35 U.S.C. 101

7. Claims 22 is rejected under **35 U.S.C. 101**, because the claimed invention is directed to non-statutory subject matter. The claim is drawn to antibody. The claim fails to recite that the claimed antibody is isolated, purified, or otherwise show the hand of the inventor. Accordingly, the claim reads on naturally occurring antibody, as it occurs occur *in vivo*, which is non-statutory subject matter. Amending the claims to recite that the antibody is isolated and purified would obviate this rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 21-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 21 provides for the use of a polypeptide in raising or selecting antibodies, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 21 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 22 is indefinite because it is not clear what is a "synthetic construct thereof" so as to allow the metes and bounds of the claims to be determined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an

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application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claim 22 is rejected under 35 U.S.C. 102(e) as being anticipated by

Wilson et al (US Patent 6,911,530, which is a divisional of 09/051,843 filed 10/23/96).

Wilson discloses a method and of making an antibody and an antibody that binds to NR4 polypeptide. The NR4 polypeptide, i.e. interleukin receptor alpha chain (SEQ ID NO:4 and 2) of Wilson have 98.9% and 72.9% query match respectively, with the polypeptide of SEQ ID NO:9 of instant application (IL-13 receptor).

Sequence comparison of SEQ ID NOs:4 and 2 (Wilson patent) with SEQ ID NO:9 (instant application) are shown below:

```

RESULT 4
US-09-688-286D-4
; Sequence 4, Application US/09688286D
; Patent No. 6911530
; GENERAL INFORMATION:
; APPLICANT: Willson, Tracey
; APPLICANT: Nicola , Nicos
; APPLICANT: Hilton, Douglas
; APPLICANT: Metcalf, Donald
; APPLICANT: Zhang , Jian
; TITLE OF INVENTION: A novel haemopoietin receptor and genetic sequences
encoding same
; FILE REFERENCE: 23199-215
; CURRENT APPLICATION NUMBER: US/09/688,286D
; CURRENT FILING DATE: 2003-07-10
; PRIOR APPLICATION NUMBER: AU PN6135
; PRIOR FILING DATE: 1995-10-23
; PRIOR APPLICATION NUMBER: AU PN7276
; PRIOR FILING DATE: 1995-12-22
; PRIOR APPLICATION NUMBER: AU PP2208
; PRIOR FILING DATE: 1996-09-09
; NUMBER OF SEQ ID NOS: 12
; SOFTWARE: PatentIn version 3.1
; SEQ ID NO 4
; LENGTH: 426
; TYPE: PRT
; ORGANISM: human
US-09-688-286D-4

```

Query Match	98.9%;	Score 2296.5;	DB 2;	Length 426;
Best Local Similarity	99.3%;	Pred. No. 2.2e-217;		

Matches 424; Conservative 0; Mismatches 2; Indels 1; Gaps 1;

US-09-688-286D-2

; Patent No. 6911530

; GENERAL INFORMATION:

; APPLICANT: Willson, Tracey

; APPLICANT: Nicola , Nicos

; APPLICANT: Hilton, Douglas

; APPLICANT: Metcalf, Donald

; APPLICANT: Zhang , Jian

; TITLE OF INVENTION: A novel haemopoietin receptor and genetic sequences encoding same

; FILE REFERENCE: 23199-215

; CURRENT APPLICATION NUMBER: US/09/688,286D

; CURRENT FILING DATE: 2003-07-10

: PRIOR APPLICATION NUMBER: AU PN6135

PRIOR FILING DATE: 1995-10-23

; PRIOR APPLICATION NUMBER: AU PN7276

; PRIOR FILING DATE: 1995-12-22

: PRIOR APPLICATION NUMBER: AU PP2208

PRIOR FILING DATE: 1996-09-09

: NUMBER OF SEO ID NOS: 12

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: SOFTWARE: PatentIn version 3.1

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; SEO ID NO 2

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; LENGTH: 424

; TYPE: PRT

Art Unit: 1646

; ORGANISM: Mus musculus
US-09-688-286D-2

Query Match 72.9%; Score 1692.5; DB 2; Length 424;
Best Local Similarity 74.6%; Pred. No. 6.6e-158;
Matches 318; Conservative 40; Mismatches 65; Indels 3; Gaps 2;

```
Qy      1 MEWPARLCGLWALLLCAGGGGGGGAAPTETQPPVTNLSVSVENLCTVIWTWNPPEGASS 60
      | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
Db      1 MARPALLGELLVLLLT--ATVGQVAAATEVQPPVTNLSVSVENLCTIIWTWSPPEGASP 58

Qy     61 NCSLWYFSHFGDKQDKKIAPETRRSIEVPLNERICLQVGSQCSTNESEKPSILVEKCISP 120
      | | : | | | | | | | | | | | | | | | | | | | | | | | | | |
Db     59 NCTLRYFSHFDDQDKKIAPETHRKEELPLDEKICLQVGSQCSANESEKPSPLVKKCISP 118

Qy    121 PEGDPESAVIELQCIWHNLSYMKCSWLPGRNTSPDNTYTLYYWHRSLKIHQCENIFREG 180
      | | | | | | | | | | | | | | | | | | | | | | | | | | | |
Db    119 PEGDPESAVTELKCIWHNLSYMKCSWLPGRNTSPDTHYTLYYWYSSLEKSRQCENIYREG 178

Qy    181 QYFGCSFDLTKVKDSSFQHQSVQIMVKDNAGKIKPSFNIVPLTSRVKPDPPHIKNLSFHN 240
      | : | | | | | | : | | : | | | | | | | | | | | | | | | |
Db    179 QHIACSFKLTKV-EPSFEHQNVQIMVKDNAGKIRPSCKIVSLTSYVKPDPPHIKHLN 237

Qy    241 DDLYVQWENPQNFRSCLFYEEVNNSQTETHNVFYVQEAACENPEFERNVENTSCFMVP 300
      | | | : | | | | | | | | | | | | | | | | | | | | | | |
Db    238 GALLVQWKNPQNFRSCLTYEEVNNTQTDRHNILEVEEDKCQNSESDRNMEGTSCFQLP 297

Qy    301 GVLPTLNTVRIVRVKTNKLCEYEDDKLWSNWSQEMSIGKKRNTLYITMLLIVPVIVADAI 360
      | | | | : | | : | | | | | | | | | | | | | | | | | | |
Db    298 GVLADAVYTVRVRVKTNKLCFDDNKLWSDWSEAQSIGKEQNSTFYTTMLLTIPVFVAVAV 357

Qy    361 IVLLLLYLKRLKIIIFPPIPDPGKIFKEMFGDQNDTLHWKKYDIYEKQTKETDSVVLIE 420
      | : | | | | | | | | | | | | | | | | | | | | | | | | | |
Db    358 IILLFYLRKRLKIIIFPPIPDPGKIFKEMFGDQNDTLHWKKYDIYEKQSKEETDSVVLIE 417

Qy    421 NLKKAS 426
      | | | | :
Db    418 NLKKA 423
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Wilson discloses:

His invention is directed to antibodies to NR4 (IL-13 receptor alpha) and its derivatives or its ligands (e.g. IL-13). Such antibodies may be monoclonal or polyclonal and may be selected from naturally occurring antibodies to NR4 or may be specifically raised to NR4 or derivatives thereof. In the case of the latter, NR4 or its derivatives may first need to be associated with a carrier molecule.

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The antibodies and/or recombinant NR4 or its derivatives of the present invention are particularly useful as therapeutic or diagnostic agents.

Antibodies to NR4 may be monoclonal or polyclonal. Alternatively, fragments of antibodies may be used such as Fab fragments. Furthermore, the present invention extends to recombinant and synthetic antibodies and to antibody hybrids. A "synthetic antibody" is considered herein to include fragments and hybrids of antibodies. The antibodies of this aspect of the present invention are particularly useful for immunotherapy and may also be used as a diagnostic tool for assessing the receptor or receptor-ligand interaction or monitoring the program of a therapeutic regimen.

Further Wilson claims antibodies specifically:

CLAIMS:

1. An isolated antibody generated using an IL-13 receptor .alpha.-chain polypeptide comprising all or part of SEQ ID NO: 4, which antibody binds to an IL-13 receptor .alpha.-chain.
2. An isolated antibody which binds specifically to an IL-13 receptor .alpha.-chain consisting of the sequence of SEQ ID NO: 4.

Therefore, many of the antibodies disclosed by Wilson will inherently bind to the polypeptide of SEQ ID NO:9 of instant application. Wilson also teaches raising antibodies that bind to the polypeptide of SEQ ID NO:9. The disclosure of meets the limitation of claim 22, absent evidence to the contrary.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aman (see IDS, J. Biol. Chem., Vol. 271, No.46, November 15, pages 29265-29270, 1996) in view of Takatsu et al (US Patent 5,453,491).

Aman discloses a polypeptide (IL-13 receptor alpha chain) which has 99.5% query match with the polypeptide of SEQ ID NO:9.

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Sequence comparison of the Aman polypeptide and SEQ ID NO:9 of instant application is disclosed below:

RESULT 1

I13R1_HUMAN

ID I13R1_HUMAN STANDARD; PRT; 427 AA.
AC P78552; O95646; Q99656;
DT 01-NOV-1997, integrated into UniProtKB/Swiss-Prot.
DT 01-MAY-1997, sequence version 1.
DT 07-MAR-2006, entry version 50.
DE Interleukin-13 receptor alpha-1 chain precursor (IL-13R-alpha-1) (IL-13RA-1) (CD213a1 antigen).
GN Name=IL13RA1; Synonyms=IL13R, IL13RA;
OS Homo sapiens (Human).
OC Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
OC Mammalia; Eutheria; Euarchontoglires; Primates; Catarrhini; Hominidae;
OC Homo.
OX NCBI_TaxID=9606;
RN [1]
RP NUCLEOTIDE SEQUENCE [MRNA].
RC TISSUE=Carcinoma;
RX MEDLINE=97165986; PubMed=9013879; DOI=10.1016/S0014-5793(96)01462-7;
RA Miloux B., Laurent P., Bonnin O., Lupker J., Caput D., Vita N.,
RA Ferrara P.;
RT "Cloning of the human IL-13R alpha1 chain and reconstitution with the
RT IL4R alpha of a functional IL-4/IL-13 receptor complex.";
RL FEBS Lett. 401:163-166(1997).
RN [2]
RP NUCLEOTIDE SEQUENCE [MRNA].
RC TISSUE=B-cell;
RA Gauchat J.F.M., Schlagenhauf E., Feng N.P., Moser R., Yamage M.,
RA Jeannin P., Alouani S., Elson G., Notarangelo L.D., Wells T.,
RA Eugster H.P., Bonnefoy J.Y.;
RL Submitted (JAN-1997) to the EMBL/GenBank/DDBJ databases.
RN [3]
RP NUCLEOTIDE SEQUENCE [MRNA].
RC TISSUE=T-cell;
RX MEDLINE=97067184; PubMed=8910586; DOI=10.1074/jbc.271.46.29265;
RA Aman M.J., Tayebi N., Obiri N.I., Puri R.K., Modi W.S., Leonard W.J.;
RT "cDNA cloning and characterization of the human interleukin 13
RT receptor alpha chain.";
RL J. Biol. Chem. 271:29265-29270(1996).
RN [4]
RP NUCLEOTIDE SEQUENCE [MRNA].
RA Wada M., Hisano T., Kuwano M.;
RL Submitted (SEP-1999) to the EMBL/GenBank/DDBJ databases.
RN [5]
RP NUCLEOTIDE SEQUENCE [LARGE SCALE MRNA].
RC TISSUE=Pancreas;
RX MEDLINE=22388257; PubMed=12477932; DOI=10.1073/pnas.242603899;
RA Strausberg R.L., Feingold E.A., Grouse L.H., Derge J.G.,
RA Klausner R.D., Collins F.S., Wagner L., Shenmen C.M., Schuler G.D.,
RA Altschul S.F., Zeeberg B., Buetow K.H., Schaefer C.F., Bhat N.K.,
RA Hopkins R.F., Jordan H., Moore T., Max S.I., Wang J., Hsieh F.,
RA Diatchenko L., Marusina K., Farmer A.A., Rubin G.M., Hong L.,
RA Stapleton M., Soares M.B., Bonaldo M.F., Casavant T.L., Scheetz T.E.,
RA Brownstein M.J., Usdin T.B., Toshiyuki S., Carninci P., Prange C.,
RA Raha S.S., Loquellano N.A., Peters G.J., Abramson R.D., Mullahy S.J.,
RA Bosak S.A., McEwan P.J., McKernan K.J., Malek J.A., Gunaratne P.H.,

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RA Richards S., Worley K.C., Hale S., Garcia A.M., Gay L.J., Hulyk S.W.,
 RA Villalón D.K., Muzny D.M., Sodergren E.J., Lu X., Gibbs R.A.,
 RA Fahey J., Helton E., Kettelman M., Madan A., Rodrigues S., Sanchez A.,
 RA Whiting M., Madan A., Young A.C., Shevchenko Y., Bouffard G.G.,
 RA Blakesley R.W., Touchman J.W., Green E.D., Dickson M.C.,
 RA Rodriguez A.C., Grimwood J., Schmutz J., Myers R.M.,
 RA Butterfield Y.S.N., Krzywinski M.I., Skalska U., Smailus D.E.,
 RA Schnerch A., Schein J.E., Jones S.J.M., Marra M.A.;
 RT "Generation and initial analysis of more than 15,000 full-length human
 RT and mouse cDNA sequences.";
 RL Proc. Natl. Acad. Sci. U.S.A. 99:16899-16903(2002).
 CC -!- FUNCTION: Binds IL13 with a low affinity. Together with IL4R-alpha
 CC can form a functional receptor for IL13. Also serves as an
 CC alternate accessory protein to the common cytokine receptor gamma
 CC chain for IL4 signaling, but cannot replace the function of gamma
 CC C in allowing enhanced IL2 binding activity.
 CC -!- SUBUNIT: Interleukin 13 receptor is a complex of IL4R, IL13RA1,
 CC and possibly other components.
 CC -!- SUBCELLULAR LOCATION: Membrane; single-pass type I membrane
 CC protein.
 CC -!- TISSUE SPECIFICITY: Ubiquitous. Highest levels in heart, liver,
 CC skeletal muscle and ovary; lowest levels in brain, lung and
 CC kidney. Also found in B-cells, T-cells and endothelial cells.
 CC -!- DOMAIN: The WSXWS motif appears to be necessary for proper protein
 CC folding and thereby efficient intracellular transport and cell-
 CC surface receptor binding.
 CC -!- DOMAIN: The box 1 motif is required for JAK interaction and/or
 CC activation.
 CC -!- SIMILARITY: Belongs to the type I cytokine receptor family. Type 5
 CC subfamily.
 CC -----
 CC Copyrighted by the UniProt Consortium, see <http://www.uniprot.org/terms>
 CC Distributed under the Creative Commons Attribution-NoDerivs License
 CC -----
 DR EMBL; Y10659; CAA71669.1; -; mRNA.
 DR EMBL; Y09328; CAA70508.1; -; mRNA.
 DR EMBL; U62858; AAB37127.1; -; mRNA.
 DR EMBL; U81379; AAD00510.3; -; mRNA.
 DR EMBL; BC009960; AAH09960.1; -; mRNA.
 DR Ensembl; ENSG00000131724; Homo sapiens.
 DR H-InvDB; HIX0017008; -.
 DR HGNC; HGNC:5974; IL13RA1.
 DR MIM; 300119; gene.
 DR GO; GO:0005898; C:interleukin-13 receptor complex; TAS.
 DR GO; GO:0005886; C:plasma membrane; TAS.
 DR GO; GO:0007166; P:cell surface receptor linked signal transdu. . .; TAS.
 DR InterPro; IPR002996; Cytkn_rcpt_B/G.
 DR InterPro; IPR003532; Hempt_rcpt_S_F2.
 DR PROSITE; PS01356; HEMATOPO_REC_S_F2; 1.
 KW Glycoprotein; Membrane; Receptor; Signal; Transmembrane:
 FT SIGNAL 1 21 Potential.
 FT CHAIN 22 427 Interleukin-13 receptor alpha-1 chain.
 FT /FTId=PRO_0000010939.
 FT TOPO_DOM 22 343 Extracellular (Potential).
 FT TRANSMEM 344 367 Potential.
 FT TOPO_DOM 368 427 Cytoplasmic (Potential).
 FT MOTIF 327 331 WSXWS motif.
 FT MOTIF 374 382 Box 1 motif.
 FT CARBOHYD 37 37 N-linked (GlcNAc. . .) (Potential).
 FT CARBOHYD 61 61 N-linked (GlcNAc. . .) (Potential).
 FT CARBOHYD 105 105 N-linked (GlcNAc. . .) (Potential).
 FT CARBOHYD 138 138 N-linked (GlcNAc. . .) (Potential).

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FT	CARBOHYD	157	157	N-linked (GlcNAc. . .) (Potential).
FT	CARBOHYD	235	235	N-linked (GlcNAc. . .) (Potential).
FT	CARBOHYD	265	265	N-linked (GlcNAc. . .) (Potential).
FT	CARBOHYD	293	293	N-linked (GlcNAc. . .) (Potential).
FT	CARBOHYD	329	329	N-linked (GlcNAc. . .) (Potential).
FT	CARBOHYD	341	341	N-linked (GlcNAc. . .) (Potential).
FT	DISULFID	46	95	Potential.
FT	DISULFID	134	144	By similarity.
FT	DISULFID	173	185	By similarity.
FT	CONFLICT	130	130	T -> I (in Ref. 3).
FT	CONFLICT	358	358	G -> D (in Ref. 3).
SQ	SEQUENCE	427 AA; 48760 MW; 5983B3E8F554107B CRC64;		

Query Match 99.5%; Score 2311; DB 1; Length 427;
Best Local Similarity 99.5%; Pred. No. 6.2e-168;
Matches 425; Conservative 0; Mismatches 2; Indels 0; Gaps 0;

Qy	1	MEWPARLCGLWALLLCAGGGGGGGAAPTETQPPVTNLSVSVENLCTVIWTWNPPEGASS	60
Db	1	MEWPARLCGLWALLLCAGGGGGGGAAPTETQPPVTNLSVSVENLCTVIWTWNPPEGASS	60
Qy	61	NCSLWYFSHFQDKQDKKIAPETRRSIEVPLNERICLQVGSQCSTNESEKPSILVEKCISP	120
Db	61	NCSLWYFSHFQDKQDKKIAPETRRSIEVPLNERICLQVGSQCSTNESEKPSILVEKCISP	120
Qy	121	PEGDPESAUIELQCIWHNLSYMKCSWLPGRNTSPDTNYTLYYWHRSLEKIHQCENIFREG	180
Db	121	PEGDPESAUIELQCIWHNLSYMKCSWLPGRNTSPDTNYTLYYWHRSLEKIHQCENIFREG	180
Qy	181	QYFGCSFDLTKVKDSSFEQHSVQIMVKDNAGKIKPSFNIVPLTSRVKPDPPHIKNLSFHN	240
Db	181	QYFGCSFDLTKVKDSSFEQHSVQIMVKDNAGKIKPSFNIVPLTSRVKPDPPHIKNLSFHN	240
Qy	241	DDLTVQWENPQNFISRCLFYEEVNNSTQETHNVFYVQEAACENPEFERNVENTSCFMVP	300
Db	241	DDLTVQWENPQNFISRCLFYEEVNNSTQETHNVFYVQEAACENPEFERNVENTSCFMVP	300
Qy	301	GVLPDTLNTVRIRVKTNKLCEYEDDKLWSNWSQEMSIGKKRNSTLYITMLLIVPVIVADAI	360
Db	301	GVLPDTLNTVRIRVKTNKLCEYEDDKLWSNWSQEMSIGKKRNSTLYITMLLIVPVIVAGAI	360
Qy	361	IVLLLYLKRLKIIIFPPIPDPGKIFKEMFGDQNDTLHWKKYDIYEKQTKETDSVVLIE	420
Db	361	IVLLLYLKRLKIIIFPPIPDPGKIFKEMFGDQNDTLHWKKYDIYEKQTKETDSVVLIE	420
Qy	421	NLKKASQ	427
Db	421	NLKKASQ	427

Aman does not teach isolated antibodies that bind IL-13-receptor alpha chain, but does disclose that the development of said antibodies may be useful in

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determining the binding of IL-4Ralpha and IL-13Ralpha (see page 29269 and 29265).

Takatsu discloses production of antibodies to IL5. The production of antibodies to polypeptides is routine in the art and Takatsu is but one of the many examples available in the prior art. Takatsu discloses the production antibodies, e.g. those that inhibited the binding of IL-5 to IL-5R

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to use the polypeptide disclosed by Aman and use the method of Takatsu to raise antibodies that bind to IL13 alpha receptor disclosed by Aman. The ordinary artisan would have been motivated to produce said antibody to study the interaction of IL4R alpha with IL-13R alpha. The ordinary artisan would have expected success at producing said antibody because antibody production is a well defined art using well established techniques. Many of the antibodies produced by using the polypeptide of Aman would inherently bind to the polypeptide of SEQ ID NO:9 of instant application due to the close homology of the two polypeptides, absent evidence to the contrary.

11. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hilton (see Proc. Natl. Acad. Sci. USA. Vol. 93, pages 497-501, January 1996) in view of Aman (IDS, J. Biol. Chem., Vol. 271, No.46, November 15, pages 29265-29270, 1996) and further in view of Takatsu et al (US Patent 5,453,491).

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Hilton discloses a polypeptide (IL-13 receptor alpha chain) which has 72.9% query match with the polypeptide of SEQ ID NO:9.

Sequence comparison of the Hilton polypeptide and SEQ ID NO:9 of instant application is disclosed below:

RESULT 9

I13R1_MOUSE

ID I13R1_MOUSE STANDARD; PRT; 424 AA.
AC O09030; Q7TT27;
DT 01-NOV-1997, integrated into UniProtKB/Swiss-Prot.
DT 01-JUL-1997, sequence version 1.
DT 07-MAR-2006, entry version 52.
DE Interleukin-13 receptor alpha-1 chain precursor (IL-13R-alpha-1) (IL-13RA-1) (Interleukin-13-binding protein) (NR4) (CD213a1 antigen).
GN Name=I13ra1; Synonyms=I113r, I113ra;
OS Mus musculus (Mouse).
OC Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi; Mammalia; Eutheria; Euarchontoglires; Glires; Rodentia; Sciurognathi; Muroidea; Muridae; Murinae; Mus.
OX NCBI_TaxID=10090;
RN [1]
RP NUCLEOTIDE SEQUENCE [MRNA].
RX MEDLINE=96133964; PubMed=8552669; DOI=10.1073/pnas.93.1.497;
RA Hilton D.J., Zhang J.-G., Metcalf D., Alexander W.S., Nicola N.A., Willson T.A.;
RT "Cloning and characterization of a binding subunit of the interleukin 13 receptor that is also a component of the interleukin 4 receptor."
RL Proc. Natl. Acad. Sci. U.S.A. 93:497-501(1996).
RN [2]
RP NUCLEOTIDE SEQUENCE [LARGE SCALE MRNA].
RC STRAIN=FVB/N; TISSUE=Brain, and Colon;
RX MEDLINE=22388257; PubMed=12477932; DOI=10.1073/pnas.242603899;
RA Strausberg R.L., Feingold E.A., Grouse L.H., Derge J.G., Klausner R.D., Collins F.S., Wagner L., Shenmen C.M., Schuler G.D., Altschul S.F., Zeeberg B., Buetow K.H., Schaefer C.F., Bhat N.K., Hopkins R.F., Jordan H., Moore T., Max S.I., Wang J., Hsieh F., Diatchenko L., Marusina K., Farmer A.A., Rubin G.M., Hong L., Stapleton M., Soares M.B., Bonaldo M.F., Casavant T.L., Scheetz T.E., Brownstein M.J., Usdin T.B., Toshiyuki S., Carninci P., Prange C., Raha S.S., Loquellano N.A., Peters G.J., Abramson R.D., Mullahy S.J., Bosak S.A., McEwan P.J., McKernan K.J., Malek J.A., Gunaratne P.H., Richards S., Worley K.C., Hale S., Garcia A.M., Gay L.J., Hulyk S.W., Villalon D.K., Muzny D.M., Sodergren E.J., Lu X., Gibbs R.A., Fahey J., Helton E., Kettelman M., Madan A., Rodrigues S., Sanchez A., Whiting M., Madan A., Young A.C., Shevchenko Y., Bouffard G.G., Blakesley R.W., Touchman J.W., Green E.D., Dickson M.C., Rodriguez A.C., Grimwood J., Schmutz J., Myers R.M., Butterfield Y.S.N., Krzywinski M.I., Skalska U., Smailus D.E., Schnerch A., Schein J.E., Jones S.J.M., Marra M.A.;
RT "Generation and initial analysis of more than 15,000 full-length human and mouse cDNA sequences."
RL Proc. Natl. Acad. Sci. U.S.A. 99:16899-16903(2002).
CC -!- FUNCTION: Binds IL13 with a low affinity. Together with IL4R-alpha can form a functional receptor for IL13. Also serves as an alternate accessory protein to the common cytokine receptor gamma chain for IL4 signaling, but cannot replace the function of gamma

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CC      C in allowing enhanced IL2 binding activity (By similarity).
CC      -!- SUBUNIT: Interleukin 13 receptor is a complex of IL4R, IL13RA1,
CC      and possibly other components (By similarity).
CC      -!- SUBCELLULAR LOCATION: Membrane; single-pass type I membrane
CC      protein.
CC      -!- TISSUE SPECIFICITY: Spleen, liver, thymus, heart, lung, kidney,
CC      testis, stomach, brain, skin, and colon; but not skeletal muscle.
CC      -!- DOMAIN: The WSXWS motif appears to be necessary for proper protein
CC      folding and thereby efficient intracellular transport and cell-
CC      surface receptor binding.
CC      -!- DOMAIN: The box 1 motif is required for JAK interaction and/or
CC      activation.
CC      -!- SIMILARITY: Belongs to the type I cytokine receptor family. Type 5
CC      subfamily.

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DR      EMBL; S80963; AAB50695.1; -; mRNA.
DR      EMBL; BC052425; AAH52425.2; -; mRNA.
DR      EMBL; BC059939; AAH59939.1; -; mRNA.
DR      Ensembl; ENSMUSG00000017057; Mus musculus..
DR      MGI; MGI:105052; Il13ra1.
DR      GO; GO:0005615; C:extracellular space; TAS.
DR      GO; GO:0016021; C:integral to membrane; TAS.
DR      InterPro; IPR002996; Cytkn_rcpt_B/G.
DR      InterPro; IPR003532; Hempt_rcpt_S_F2.
DR      PROSITE; PS01356; HEMATOPO_REC_S_F2; 1.
KW      Glycoprotein; Membrane; Receptor; Signal; Transmembrane.
FT      SIGNAL          1           25      Potential.
FT      CHAIN           26          424      Interleukin-13 receptor alp
FT                                          /FTid=PRO_0000010940.
FT      TOPO_DOM        26          340      Extracellular (Potential).
FT      TRANSMEM        341         364      Potential.
FT      TOPO_DOM        365         424      Cytoplasmic (Potential).
FT      MOTIF           324         328      WSXWS motif.
FT      MOTIF           371         379      Box 1 motif.
FT      CARBOHYD        35          35      N-linked (GlcNAc. . .) (Pot
FT      CARBOHYD        59          59      N-linked (GlcNAc. . .) (Pot
FT      CARBOHYD        103         103      N-linked (GlcNAc. . .) (Pot
FT      CARBOHYD        136         136      N-linked (GlcNAc. . .) (Pot
FT      CARBOHYD        262         262      N-linked (GlcNAc. . .) (Pot
FT      CARBOHYD        338         338      N-linked (GlcNAc. . .) (Pot
FT      DISULFID        44          93      Potential.
FT      DISULFID        132         142      By similarity.
FT      DISULFID        171         183      By similarity.
SQ      SEQUENCE        424 AA;  48402 MW;  EB8330A0DC82C9F9 CRC64;

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Qy	1	MEWPARLCGLWALLLCAGGGGGGGAAPTETQP	PVTNLSVSVENLCTVIWTNPPEGASS	60
		:	:	
Db	1	MARPALLGELLVLLLT--ATVGQVAATEVQP	PVTNLSVSVENLCTIIWTSPPEGASP	58
Qy	61	NCSLWFYFSHFQDKQDKKIAPETRRSIEVPLNERICLQVGSQCSTNESEKPSILVEKCISP	120	
		: : : :		
Db	59	NCTLRIFYSHFDDQDQDKKIAPETHRKEELPLDEKICLQVGSQCSANESEKPSPLVKKCISP	118	
Qy	121	PEGDPESAVIELQCIWHNLSYMKCSWLPGRNTSPDTNYTLYYWHRSLLEIKHQECENIFREG	180	
		: : : :		

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Db      119 PEGDPESAVTELKCIWHNLSYMKCSWLPGRNTSPDTHYTLYYWYSSLEKSRQCENIYREG 178
Qy      181 QYFGCSFDLTKVKDSSFEQHSVQIMVKDNAGKIKPSFNIVPLTSRVKPDPPHIKNLSFHN 240
      |: ||| |||| : ||| :||| ||||| |||||: || ||| ||||| |||||:|
Db      179 QHIACSFKLTKV-EPSFEHQNVQIMVKDNAGKIRPSCKIVSLTSYVKPDPPHIKHLN 237
Qy      241 DDLYVQWENPQNFI SRCLFYEEVNNSQTETHNVFYVQEAKCENPEFERNVENTSCFMVP 300
      | |||: |||| | ||| ||||| |||||: ||| ||| :| |||: | ||| :|
Db      238 GALLVQWKNPQNFRSRCLTYEEVNNTQTDRHNILEVEEDKCQNSESDRNMEGTSCFQLP 297
Qy      301 GVLPTDLNTVRIRVKTNKLCEYEDDKLWSNWSQEMSIGKKRNSTLYITMLLIVPVIVADAI 360
      ||| | : |||: ||||| |||: |||: |||: |||: |||: ||| | ||| :|| ||| :
Db      298 GVLADAVYTVRVRVKTNKLCFDDNKLWSDWSEAQSIGKEQNSTFYTTMLLTIPVFAVAV 357
Qy      361 IVLLLYLKRLKIIIFPPIPDPGKIFKEMFGDQNDLTHWKKYDIYEKQTKETDSVVLIE 420
      |: || ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| |||||
Db      358 IILLFYLKRLKIIIFPPIPDPGKIFKEMFGDQNDLTHWKKYDIYEKQSKETDSVVLIE 417
Qy      421 NLKKAS 426
      |||||:
Db      418 NLKKA 423

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Hilton discloses a NR4 polypeptide (IL-13 receptor) which binds IL-13 and together with IL-4R-alpha can form a functional receptor for IL-13 (see Fig 1, Abstract and Discussion). Hilton does not disclose isolated antibodies that bind (IL-13 receptor alpha chain

Aman discloses that isolated antibodies that bind IL-13 receptor alpha may be useful in determining the binding of IL-4Ralpha and IL-13Ralpha (see page 29269 and 29265).

Takatsu discloses production of antibodies to IL5. The production of antibodies to polypeptides is routine in the art and Takatsu is but one of many examples. The inventors used various methods and produced monoclonal antibodies which inhibited the binding of IL-5 to IL-5R

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to take the polypeptide disclosed by Hilton and by using the method of Takatsu raise antibodies that bind to IL13 alpha receptor disclosed by Hilton. The ordinary artisan would have been motivated to

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produce said antibody to study the interaction of IL4R alpha with IL-13R alpha as disclosed by Aman.

The ordinary artisan would have expected success at producing said antibody because antibody production is a well defined art using well established techniques. Many of the antibodies produced by using the polypeptide of Hilton would inherently bind to the polypeptide of SEQ ID NO:9 of instant application due to the close homology of the two polypeptides, absent evidence to the contrary.

12. No claim is allowed.

13. ***Priority***

Applicant is reminded that in order for a patent issuing on the instant application to obtain the benefit of priority based on priority papers filed in parent Application No. 08/969,125 under 35 U.S.C. 119(a)-(d) or (f), a claim for such foreign priority must be timely made along with a certified copy of the foreign application. To satisfy the requirement of 37 CFR 1.55(a)(2) for a certified copy of the foreign application, applicant may simply identify the application containing the certified copy. It is noted that claim to foreign priority is made but the United Kingdom Application 9625899.1 is not attached. Appropriate correction is required.

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Advisory

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 571-272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nirmal S. Basi
Art Unit 1646
12/11/06

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